

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ORVILLE SMITH,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY,
SANOFI-AVENTIS U.S. L.L.C.,
SANOFI-AVENTIS U.S., INC.,
SANOFI-SYNTHELABO, INC.,

Defendants.

:
:
: Civil Action No. 3:06-cv-6053 (FLW)
:

OPINION

:
:
:
:
:
:
:
:
:
:
:
:
:

This matter comes before the Court on a motion to dismiss pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure brought by defendants, Bristol Myers-Squibb Company, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc., (collectively, “Defendants”). Plaintiff Orville Smith’s First Amended Complaint asserts claims against Defendants for: (1) negligence (Count I); (2) negligent misrepresentation (Count II); (3) violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law (Count III); and (4) punitive damages (Count V).¹ Plaintiff alleges that he was injured as a result of Defendants’ unlawful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of the prescription drug Plavix®. Defendants’ motion to dismiss is limited to Counts II and III of Plaintiff’s Complaint. For the reasons that follow, Defendants’ motion to dismiss Counts II and III is granted.

¹ Plaintiff’s First Amended Complaint does not allege a Fourth Count.

I. Procedural History

On December 18, 2006, Plaintiff, a Pennsylvania resident, filed a Complaint against Defendants asserting claims under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq.*, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*, the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, *et seq.*, New Jersey's Uniform Commercial Code, N.J.S.A. 12A:2-313, and the common law of the State of New Jersey, invoking this Court's diversity jurisdiction. (Dec. 18, 2006 Complaint ¶¶ 6-8.) Plaintiff is one of twenty-three individual claimants² that lodged separate complaints³ against Defendants in this district between October 2006 and March 2007, invoking this Court's diversity jurisdiction and asserting similar claims under New Jersey law based upon injuries allegedly suffered as a result of Defendants' alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix. *Id.* A brief recitation of the procedural history in the related matters is necessary to a full understanding of the prolonged procedural history in this matter.

In January 2007, Defendants filed motions to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) in the matters of Hall v. Bristol-Myers Squibb, No. 06-CV-5203 (hereinafter, "Hall"), and Skilstaff v. Bristol-Myers Squibb, No. 06-CV-4965 (hereinafter, "Skilstaff"),⁴

² Initially, claims were filed on behalf of twenty-four individual claimants, however, a Michigan plaintiff in the matter of Felmlee v. Bristol-Myers Squibb Co., No. 06-6240, voluntarily dismissed her claim in February, 2008.

³ A number of the twenty-three claimants were joined in their actions by spouses, asserting claims for loss of consortium.

⁴ The plaintiff in the matter of Skilstaff v. Bristol-Myers Squibb, is not among the twenty-three individual claimants seeking damages for personal injuries, rather Skilstaff was an Alabama third-party payor seeking certification of a class of third-party

and indicated their intention to file similar motions in the other Plavix cases pending before this Court. In March 2007, this Court, without objection from the parties, administratively terminated Defendants' motions in Hall and Skilstaff having determined that two cases then pending before the New Jersey Supreme Court addressed the central issues to be decided by this Court on Defendants' motions to dismiss. The parties further agreed that all Plavix cases filed in this district be held in abeyance. Following the issuance of the New Jersey Supreme Court's decisions in Rowe v. Hoffman-LaRoche, 189 N.J. 615 (2007), and International Union of Operating Engineers, Local #68 v. Merck, 192 N.J. 372 (2007), the plaintiff in Skilstaff voluntarily dismissed the action and this Court granted Defendants' request to file a single omnibus motion to dismiss applicable to all personal injury Plavix lawsuits then pending in this district.

One of the main issues to be determined by this Court in the omnibus motion was the federal preemption of the plaintiffs' individual state law claims. In February 2008, however, in light of the fact that the Third Circuit had pending two separate cases, Colacicco v. Apotex, Inc., and McNellis ex. rel. DeAngelis v. Pfizer, Inc., on its docket regarding substantially similar preemption issues, as did the United States Supreme Court, Levine v. Wyeth, this Court administratively terminated the personal injury Plavix cases pending in this district and permitted plaintiffs to re-file amended complaints in the event there were viable claims after the decisions from the Higher Courts. Following the issuance of the Supreme Court's decision in Levine v. Wyeth, __ U.S. __, 129 S.Ct. 1187, 173 L.Ed. 2d 51 (2009), this Court reinstated the closed cases and, on May 1, 2009, each of the plaintiffs filed an amended complaint. In the amended complaints, each individual

payors for violations of the New Jersey Consumer Fraud Act.

plaintiff brought claims under the laws of the states in which they reside, rather than New Jersey, as originally plead. Thereafter, Defendants moved to dismiss certain counts of the amended complaint filed by each individual plaintiff. It is the Defendants' motion to dismiss Counts II and III with regard to this Plaintiff that this Court now considers.

II. Factual Background

The following version of events assumes Plaintiff's allegations in the First Amended Complaint ("FAC") to be true because Defendants move pursuant to Fed. Civ. R. P. 12(b)(6). The Court will recount only those facts relevant to this Motion.

Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, the "Sanofi Defendants") partnered with Bristol-Myers Squibb Company ("BMS") to manufacture and market Plavix in the United States. FAC ¶¶ 2-4. In April 1997, the Sanofi Defendants and BMS applied for a rare, priority regulatory review by the Food and Drug Administration ("FDA") clearing the way for Defendants to bring Plavix to market in November 1997. Id. at ¶ 11. According to Plaintiff, Defendants heavily marketed Plavix directly to consumers through television, magazine, and Internet advertising, falsely touting Plavix "as a 'super-aspirin' that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person's stomach than aspirin." Id. at ¶ 13. Plaintiff alleges that Defendants either knew or should have known, based upon their own studies, that not only was Plavix not more efficacious than aspirin in terms of preventing heart attacks and strokes, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder or death far outweighed any benefit from the drug. Id. at ¶ 14.

As evidence that Defendants were indeed aware of their false and misleading

promotion of Plavix, Plaintiff points to a November 1998 letter from the FDA wherein the FDA instructed Defendants to cease promoting Plavix for off-label use in patients undergoing coronary artery stent placement.⁵ Id. at ¶ 18; Certification of Michele A. DiMartino, Esq. (“DiMartino Cert.”) at ¶ 4, Ex. C. Plaintiff also points to the same FDA reprimand wherein Defendants were instructed to cease promoting Plavix at an off-label dose, which was nearly four (4) times that of the recommended dosage. FAC at ¶ 18; DiMartino Cert. ¶ 4, Ex. C. In addition to criticizing Defendants for promoting Plavix for unapproved use, the FDA also criticized Defendants for overstating the safety profile of Plavix with respect to its use with other drugs. Id. at ¶ 19. In particular, Plaintiff points to the fact that Defendants touted the safety of Plavix when combined with aspirin (known as “dual therapy”) when, in fact, its safety had not been established. Id. According to Plaintiff, Defendants’ claim regarding the safety of dual therapy has now been proven untrue in a recent study published in the New England Journal of Medicine in April 2006 entitled Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance (the “CHARISMA Study”⁶). FAC at ¶ 19; DiMartino Cert. at ¶ 3, Ex. B.

As further evidence of Defendants’ allegedly false and misleading promotional practices, Plaintiff points to a December 1998 letter from the FDA, wherein the FDA demanded that Defendants cease the distribution of advertising materials that claimed

⁵ As discussed more fully infra, the Court will consider the extrinsic documents referenced in the FAC as they were explicitly relied upon by Plaintiff in the FAC.

⁶ The CHARISMA Study derives its name from the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance trial, which was the subject of the article.

that Plavix has been proven more effective than aspirin. FAC at ¶ 20; DiMartino Cert. at ¶ 2, Ex. A. The FDA criticized Defendants' materials as an overstatement of efficacy, which was unsubstantiated and lacking in fair balance. Id. Again in 2001, the FDA ordered Defendants to immediately cease distribution of promotional material that made false or misleading claims about Plavix. FAC at ¶ 21; DiMartino Cert. at ¶ 5, Ex. D. Specifically, the FDA noted that the clinical evidence of the efficacy of Plavix is derived from Defendants' study entitled Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events Trial (the "CAPRIE Study"). Id. Defendants' promotional material depicted a 19.2% relative risk reduction for Plavix versus aspirin, yet the actual findings of the CAPRIE Study were that Plavix was not proven significantly more effective than aspirin. Id. Additionally, the FDA again instructed Defendants to cease claiming that the use of Plavix combined with aspirin was safe and effective. Id.

According to Plaintiff, in addition to misinforming physicians and consumers through false and misleading promotional materials and advertising, Defendants' drug representatives also misinformed physicians regarding the proper types of patients who should be prescribed Plavix, the duration of its proper usage and the applications for which Plavix is safe and FDA approved. FAC at ¶ 22. Specifically, Plaintiff points to the fact that the drug representatives have encouraged physicians to prescribe Plavix to a broad population who would receive the same therapeutic benefit from aspirin alone, without the purported risk of death, and to use Plavix for unapproved applications. Id. at ¶ 23.

Plaintiff alleges that after a nearly eight-year run of misleading physicians and the public regarding the safety and efficacy of Plavix, scientific studies now reveal that Plavix is in fact dangerous. Id. at ¶ 25. Citing a study published in The New England Journal of

Medicine in January 2005 entitled Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding (the “Chan Study”), Plaintiff notes the dangers of Plavix.

Specifically, Plaintiff contends that the Chan Study demonstrates the fallacy of Defendants’ assertions that Plavix is safer and more effective for patients suffering from gastrointestinal intolerance to aspirin. Id. at ¶ 26. Plaintiff points out that the Chan Study recommended that prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin, in light of the Study’s findings that recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Id. Plaintiff additionally points to the Chan Study’s finding that an aspirin a day plus esomeprazole (the generic name for an inexpensive over-the-counter proton pump inhibitor such as Prilosec) is far more cost effective than paying for the four-dollar per day Plavix pill, which greatly increases the risk of stomach bleeding. Id. at ¶ 27. Finally, citing the CHARISMA Study, Plaintiff contends that Plavix plus aspirin (“dual therapy”) is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events, and more significantly, does more harm than good in those patients without peripheral arterial disease or acute coronary syndrome in that it poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. Id. at ¶ 28.

Plaintiff contends that “[i]n or around the month of July, 2005, [he] was prescribed Plavix for a bypass and stenting procedure. From that date on, he took Plavix in combination with a daily aspirin (known as ‘dual therapy’). On or about June 6, 2006, severe internal hemorrhaging caused him to permanently lose sight in his left eye.” Id. at ¶ 30. With regard to his own experiences, or those of his prescribing physician, in

connection with Defendants' purported false and misleading promotional materials and practices, Plaintiff's limited discussion of those facts will be discussed more fully infra.

III. Standard of Review

When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Id. at 561 (quoting Conley, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 555. As the Third Circuit has stated, "[t]he Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of 'the necessary element'." Phillips, 515 F.3d at 234 (quoting Twombly, 550 U.S. at 556).

In affirming that Twombly standards apply to all motions to dismiss, the Supreme Court recently explained the principles. "First, the tenet that a court must accept as true

all of the allegations contained in a complaint is inapplicable to legal conclusions.”

Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949, 173 L.Ed. 2d 868 (2009); Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).⁷ “Second, only a complaint that states a plausible claim for relief survives a motion to dismiss.” Id. at 1950. Therefore, “a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth.” Id. Ultimately, “a complaint must do more than allege the plaintiff’s entitlement to relief. A complaint has to ‘show’ such an entitlement with its facts.” Fowler, 578 F.3d at 211.

Before reaching the merits of Plaintiff’s claims, there is a threshold procedural question as to the documents and exhibits this Court may consider on this motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6). As previously referenced in this Court’s discussion of the Factual Background, Plaintiff supplies this Court with several exhibits, including: (1) a December 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (2) a copy of the CHARISMA Study; (3) a November 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (4) a May 2001 FDA letter addressed to Sanofi-Synthelabo Inc.; and (5) the Chan Study. Additionally, the Defendants provide the Court with the November 17, 1997 approval letter for Plavix. Certification of Michael A. Tanenbaum, Esq., Ex. A. While generally a court may not consider matters outside the pleadings when ruling on a motion to dismiss, documents that are “integral to or explicitly relied upon in the complaint” may indeed be considered without converting a motion to dismiss into a motion for summary

⁷ The Court notes that because the briefing in this matter was filed only shortly after the United States Supreme Court’s decision in Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009), counsel for Defendants moved for leave to file supplemental briefing addressing the standard of review applicable to the instant motion. This Court found additional briefing unnecessary and, accordingly, denied Defendants’ request.

judgment. In re Rockefeller Ctr. Props., Inc. Sec. Litig., 184 F.3d 280, 287 (3d Cir.1999) (emphasis and citations omitted). Accordingly, the referenced exhibits are properly before the Court on the instant motion to dismiss.

IV. Plaintiff's Claim Under Pennsylvania's Unfair Trade Practices and Consumer Protection Law

In Count III of Plaintiff's FAC, Plaintiff asserts violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 PA Cons. Stat. §§ 201-1, *et seq.* Defendants seek dismissal of Plaintiff's UTPCPL claim, arguing that Pennsylvania courts have determined that the UTPCPL does not apply to claims brought against manufacturers of prescription drugs. Additionally, Defendants contend that the UTPCPL claim lacks the particularity required by Fed.R.Civ.P. 9(b).

"The UTPCPL makes unlawful unfair methods of competition and deceptive practices in the conduct of trade or commerce." Albertson v. Wyeth Inc., No. 2944, 2003 WL 21544488, *11 (Pa.Ct.Com.Pl. Jul. 8, 2003) (citing Luke v. American Home Products Corp., No. 1998-C-01977, 1998 WL 1781624, *8 (Pa.Ct.Com.Pl. Nov. 18, 1998)). The UTPCPL "provides a means of redress for various misrepresentations and fraudulent conduct that create a likelihood of confusion or misunderstanding." Id. Citing to Booze v. Allstate Insurance Company, 750 A.2d 877 (Pa. Super. 2000), Plaintiff contends that to establish a claim under the UTPCPL, he need only prove the elements of common law fraud. Pl. Br. at 8. According to Plaintiff, the FAC, as a whole, satisfies those requisite elements, namely: material representation of an existing fact, scienter, justifiable reliance upon the misrepresentation; and damages. Id. Additionally, Plaintiff contends that the FAC "easily satisfies the particularity requirements of Fed.R.Civ.P. 9(b). Id. at 10.

The Court turns first to Defendants' contention that Plaintiff's UTPCPL claim fails

as a matter of law because Pennsylvania courts have excluded prescription drugs from the protections afforded by the UTPCPL. In Luke v. American Home Products Corp., No. 1998-C-01977, 1998 WL 1781624, *8 (Pa.Ct.Com.Pl. 1998), a plaintiff brought suit against defendants who designed, manufactured, marketed, promoted and distributed a prescription drug that plaintiff claimed caused her debilitating health effects. Considering whether the plaintiff could maintain an action against the defendant drug manufacturers under Pennsylvania's UTPCPL, the Luke court held that an action could not lie against the defendants for any alleged omissions because they owed "no duty to disclose any information directly to [p]laintiff." Luke, 1998 WL 1781624, at *8. That finding was based upon the court's application of the learned intermediary doctrine. Indeed, the Luke court held that "[u]nder the 'learned intermediary doctrine,' a manufacturer of prescription drugs must direct information and warnings to *prescribing physicians*, not the patient." Id. (Emphasis in original). The Luke court went on to note:

to permit a cause of action under the UTPCPL in this case would effectively make a drug manufacturer the absolute guarantor of the anticipated results and effects of a prescription drug. Pennsylvania law, however, recognizes that some prescription drugs by their very nature can never be made safe. An inconsistency would result if we were to hold that drug manufacturers must guarantee that prescriptions drugs are completely safe. The premise behind the UTPCPL was not meant to engender such a result.

Id. (*internal citations omitted*).

The applicability of the learned intermediary doctrine to claims brought against a prescription drug manufacturer under the UTPCPL was again revisited in Albertson v. Wyeth Inc., No. 2944, 2003 WL 21544488, *11 (Pa.Com.Pl. Jul. 8, 2003), wherein the plaintiff urged a Pennsylvania court to create a limited exception to the doctrine "where

direct-to-consumer advertising is used.” Citing Luke, the Albertson court declined to create an exception to the learned intermediary doctrine based upon direct-to-consumer advertising, noting that:

[m]edia dissemination of information concerning the existence of these drugs does not enhance the public’s ability to acquire them, as the skill and knowledge of the physician still must be brought to bear in a determination of whether the pharmaceutical is appropriate for the patient. Lennon ex rel. v. Wyeth-Ayerst Laboratories, Inc., 2001 WL 755944, *2 (Pa.Super. 2001). Here, although [the defendant] engaged in direct-to-consumer advertising, the consumer still required a prescription from a physician, a learned intermediary, to acquire [the drug].

Albertson, 2003 WL 21544488, *12; see also Heindel v. Pfizer, 381 F.Supp.2d 364, 384 (D.N.J. 2004) (finding plaintiff’s claims involving direct-to-consumer prescription drug advertising barred by learned intermediary doctrine). It is clear that the learned intermediary doctrine indeed operates to bar Plaintiff’s UTPCPL claim.

Although this Court need not address the sufficiency of Plaintiff’s pleading under Rule 9(b) given the finding that Plaintiff may not maintain a cause of action under the UTPCPL, the Court will nevertheless do so in the interest of completeness. To establish a cause of action under the UTPCPL, Plaintiff must plead “with the same specificity as common law fraud.” Gilmour v. Bohmueller, No. 04-2535, 2005 WL 241181, *11 (E.D.Pa. Jan. 27, 2005). The parties do not dispute that “to assert a cause of action pursuant to the UTPCPL, a plaintiff must allege the following essential elements of fraud: ‘(1) material misrepresentation of a material fact; (2) scienter; (3) intention by the declarant to induce action; (4) justifiable reliance by the party defrauded upon the misrepresentation; and

damages to the party defrauded as a proximate result.’”⁸ Id. Nor do the parties dispute the applicability of Rule 9(b) to Plaintiff’s UTPCPL claim.

In Frederico v. Home Depot, 507 F.3d 188 (3d Cir. 2007), the Third Circuit elucidated what must be alleged to satisfy the heightened pleading standard of Rule 9(b):

Pursuant to Rule 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the “precise misconduct with which [it is] charged.” To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.

Id. at 200 (internal citations omitted). The Court finds the FAC woefully deficient. As Defendants indicate, Paragraph 30 of the FAC is the only paragraph in the entire FAC that provides specific details regarding Plaintiff and not one of those details concerns the UTPCPL claim.⁹ The remaining factual allegations are boilerplate allegations that, as Defendants point out, appear in all twenty-three of the amended complaints filed by the personal injury Plavix plaintiffs in this district. The allegations within Count III of the FAC do not remedy the deficiency. The allegations amount to nothing more than a

⁸ As previously noted, the UTPCPL “makes it unlawful for individuals or businesses to engage in unfair or deceptive acts or practices.” Baker v. Family Credit Counseling Corporation, 440 F.Supp.2d 392,412 (E.D.Pa. 2006). Unfair or deceptive practices consist of a variety of actions under the UTPCPL. Id. Therefore, “[w]hat a plaintiff must include in a complaint in order to allege a violation of the UTPCPL depends on which section of the UTPCPL a defendant allegedly violated.” Id. Plaintiff does not identify in the FAC which specific sections of the UTPCPL Defendants purportedly violated. Regardless, however, in order to allege a violation under any provision of the UTPCPL, a plaintiff “must allege both reliance and causation.” Id. Because the Court finds, infra, that Plaintiff has failed to plead those elements with the particularity required by Rule 9(b), it need not address which particular provisions of the UTPCPL are at issue.

⁹ As previously noted, Paragraph 30 provides: “[i]n or around the month of July, 2005, Plaintiff Orville Smith was prescribed Plavix for a bypass and stenting procedure. From that date on, he took Plavix in combination with a daily aspirin (known as ‘dual therapy’). On or about June 6, 2006, severe internal hemorrhaging caused him to permanently lose sight in his left eye.” FAC at ¶ 30.

mechanical recitation of the elements of a cause of action under the UTPCPL. Indeed, there is absolutely no plaintiff-specific information identified in Count III.

Citing U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co., 147 F.Supp. 2d 39, 49 (D.Mass.2001), Plaintiff urges this Court to find that the circumstances present in this case warrant the relaxation of the particularity requirements of Rule 9(b). Pl. Br. at 7. To the extent that the requirements of Rule 9(b) may be relaxed, the Court finds relaxation inappropriate here. The facts necessary to satisfy Rule 9(b) are not facts which are in Defendants' control. Rather, what Plaintiff has failed to allege are those facts that demonstrate that either Plaintiff or his prescribing physician relied upon any of the purported misrepresentations and/or omissions.¹⁰ Plaintiff identifies Paragraphs 71 and 74 of the FAC as supportive of the fact that the element of justifiable reliance has been plead with particularity. Those Paragraphs provide:

71. The Defendants' statements and omissions were made with the intent that the Plaintiff, and Plaintiff's prescribing physician, would rely on them.

....

74. By reason of Defendants' acts, uses and employment of deception, unfair and deceptive practices, fraud, false promises,

¹⁰ Indeed, in that connection, Plaintiff is uniquely equipped to determine from his prescribing physician, whether the physician received such promotional literature or information from Defendants' sales representatives. Even where factual information may be within the domain or control of Defendants, Plaintiff must still "accompany [his] legal theory with factual allegations that make [his] theoretically viable claim plausible." In re Burlington Coat Factory, 114 F.3d 1410, 1418 (3d Cir. 1997). Moreover, to "avoid dismissal," a complaint must also delineate at least the nature and the scope of a plaintiff's efforts to obtain, before filing the complaint, the information needed to plead with particularity. Shapiro v. UJB Financial Corp., 964 F.2d 272, 285 (3d Cir. 1992). Plaintiff has failed to comply with these requirements. Plaintiff's FAC makes no allegations that the information required for Plaintiff to meet his Rule 9(b) obligation is solely within Defendants' control.

misrepresentations, concealment, suppression and omission of material facts, reasonable patients/consumers acting reasonably, such as Plaintiff, were caused to rely upon same and purchase and ingest the Plavix, and thereby sustain serious personal injuries.

Clearly Plaintiff has failed to satisfy the particularity requirements with respect to justifiable reliance and causation. While Plaintiff asserts in Paragraph 71 that Defendants' statements were made with the intent that Plaintiff and his prescribing physician rely on them, he never asserts in Paragraph 74 that his prescribing physician relied on those statements. Indeed, Plaintiff does not even identify the name of the prescribing physician. Plaintiff limits the reliance assertions in Paragraph 74 to his own purported reliance, yet other than the conclusory allegation that he relied on Defendants' unfair and deceptive practices, he offers no information whatsoever with regard to that reliance. Nor does Plaintiff address the fact that the promotional materials, referenced in the 1998 and 2001 FDA letters and cited in the Complaint, were disseminated four to six years prior to Plaintiff's prescription for Plavix. While it is true that when reviewing a motion to dismiss, the Court must construe the complaint in the light most favorable to the plaintiff, Phillips, 515 F.3d at 233, in the absence of specific facts in the FAC that Plaintiff or his prescribing physician relied upon the promotional materials that the FDA demanded Defendants discontinue disseminating four to six years prior to Plaintiff's prescription, the Court simply cannot find that the particularity requirements have been met. Accordingly, Plaintiff's UTPCPL claim cannot withstand the instant motion to dismiss.¹¹

¹¹ Defendants also sought dismissal of Plaintiff's punitive damages claim to the extent it sought punitive damages under the UTPCPL. In light of this Court's dismissal of Plaintiff's UTPCPL claim, this Court need not address the issue, however, the Court notes, and Plaintiff does not contest, that punitive damages are unavailable under the UTPCPL.

V. Plaintiff's Negligent Misrepresentation Claim

“Negligent misrepresentation requires proof of (1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation.” Bionix Development Corporation v. Sklar Corporation, No. 07-4465, 2009 WL 3353154, *4 (E.D.Pa. Oct. 14, 2009) (citing Bortz v. Noon, 729 A.2d 555 (Pa. 1999)).¹² “A claim for negligent misrepresentation fails in the absence of a duty to disclose.” Id.

Plaintiff does not dispute that he must establish that Defendants had a duty to disclose. Indeed, Plaintiff cites Althaus v. Cohen, 756 A.2d 1166, 1169 (2000), which sets forth the contours of when a duty exists, in support of his contention that Defendants owed him a duty “to provide accurate, truthful information consistent with the scientific studies

¹² Addressing the elements of his negligent misrepresentation claim, Plaintiff cites the Restatement (Second) of Torts § 552 (1977). The requisite elements of § 552 differ slightly from the common law elements applied in Bortz v. Noon, 729 A.2d 555 (1999), which had been routinely applied to Pennsylvania negligent misrepresentation claims prior to the Pennsylvania Supreme Court’s most recent application of § 552. Brandow Chrysler Jeep Company v. Datascan Technologies, 511 F.Supp.2d 529, 536 (E.D.Pa. 2007) (citing Bilt-Rite Contractors v. Architectural Studio, 581 Pa. 454, 866 A.2d 270, 287 (2005)). Essentially, the Pennsylvania Supreme Court adopted § 552 “in cases where information is negligently supplied by one in the business of supplying information . . . and where it is foreseeable that the information will be used and relied upon by third persons, even if the third parties have no direct contractual relationship with the supplier of information.” Bilt-Rite, 866 A.2d at 287. However, the Bilt-Rite court adopted § 552 as it applies to architects and other design professionals. Id. Plaintiff has cited no authority to support its application here where Defendants are not design professionals or, at the very least, in the business of supplying professional information for use by others. See, e.g., Brandow, 511 F.Supp.2d at 537 (applying § 552 to negligent misrepresentation claim brought against firm specializing in professional field audit services). This Court does not find Bilt-Rite applicable to the instant matter and, accordingly, will apply those elements of negligent misrepresentation enunciated by the Pennsylvania Supreme Court in Bortz v. Noon, 729 A.2d 555 (1999).

and to only promote their drugs for approved uses and to place safety of human beings above profit.” Pl. Br. at 13-14. What Plaintiff fails to address, however, is the application of the learned intermediary doctrine. Pointing to Luke, 1998 WL 178 1781624 at *8 and Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1970), *abrogated on other grounds by Kaczowski v. Bolubasz*, 421 A.2d 1027 (1980), Defendants urge this Court to apply the learned intermediary doctrine to Plaintiff’s negligent misrepresentation claim to find the Defendants’ duty ran only to Plaintiff’s prescribing physician.

“It is well-settled that under Pennsylvania’s ‘learned intermediary doctrine,’ the duty of a drug manufacturer to warn of the possible dangers and side effects of prescription drugs runs to the physician and not to the patient or to the general public.” Kline v. Pfizer, Inc., No. 08-3238, 2008 WL 4787577, * 3 (E.D.Pa. Oct. 31, 2008) (*citations omitted*).

Indeed,

[a] prescription drug manufacturer has “a duty to exercise reasonable care to inform those for whose use the article [was] supplied of the facts which make [the product] likely to be dangerous . . .’ However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer.” This is so because the physician acts as a “learned intermediary” between the manufacturer and consumer, and can use the information obtained from the manufacturer, as well as his independent medical knowledge and knowledge of the patient’s medical history, in deciding whether or not to prescribe a certain prescription to a certain patient.

Id. (*quoting Makripodis v. Merrell-Dow Pharm. Co.*, 523 A.2d 374, 378 (Pa.Super. 1987)) (*internal citations omitted*). Accordingly, while Defendants owed no duty to warn Plaintiff, or the public, Defendants may still be held liable under a theory of negligent misrepresentation if Plaintiff can prove that Defendants breached their duty to Plaintiff’s prescribing physician. While it is clear that the learned intermediary doctrine operates to bar claims brought by personal injury plaintiffs against prescription drug manufacturers

under the UTPCPL, see Albertson v. Wyeth Inc., 2003 WL 21544488, at *12, the doctrine does not similarly bar plaintiffs from maintaining a negligent misrepresentation claim based upon a defendant's breach of the duty of care owed to a plaintiff's prescribing physician. See Kline v. Pfizer, Inc., 2008 WL 4787577, at * 3 (finding negligent misrepresentation claim survives motion to dismiss where plaintiff alleges drug manufacturer failed to adequately warn plaintiff's health care providers).¹³

Nevertheless, Plaintiff's negligent misrepresentation claim based on Defendant's failure to adequately warn his prescribing physician can only survive the instant motion to dismiss if it satisfies the pleading requirements. Citing Hanover Ins. Co. v. Ryan, 2007 WL 4456158 at *9 (E.D.Pa. Dec. 17, 2007), Defendants contend that like the UTPCPL claim, Plaintiff's negligent misrepresentation claim is subject to the particularity requirement of Rule 9(b). Defendants argue that because Plaintiff's negligent misrepresentation claim sounds in fraud, the heightened standards of Rule 9(b) apply. However, Hanover Ins. Co. v. Ryan, 2007 WL 4456158 at *9 is the lone case that applies Rule 9(b) to a negligent misrepresentation claim brought under Pennsylvania law. In fact, generally courts in this circuit that have addressed the issue have found the particularity requirements of Rule

¹³ The distinction between UTPCPL claims, which fail under Pennsylvania law in prescription drug cases, and negligent misrepresentation claims which may survive despite the application of the learned intermediary doctrine where the allegations are such that a defendant drug manufacturer failed to adequately warn a prescribing physician, appears to lie in the underpinnings of the UTPCPL. The courts that have applied the learned intermediary doctrine to bar claims brought under the UTPCPL against prescription drug manufacturers have expressly recognized that the premise behind the UTPCPL was not meant to make drug manufacturers "the absolute guarantor of the anticipated results and effects of" prescription drugs, some of which by their very nature may never be made safe. See Albertson v. Wyeth Inc., 2003 WL 21544488, at *12; see also Luke, 1998 WL 1781624, at *8.

9(b) inapplicable to a negligent misrepresentation claim brought under Pennsylvania law. See Sims v. Viacom, Inc., No. 09-3521, 2009 WL 3856667, *2 (E.D.Pa. Nov. 17, 2009); Bionix Development Corporation v. Sklar Corporation, 2009 WL 3353154, *3; Brandow, 511 F.Supp.2d at 537; TruePosition, Inc. v. Sunon, Inc., No. 05-3023, 2006 WL 1451496, *4 (E.D.Pa. May 25, 2006); McHale v. NuEnergy Group, No. 01-4111, 2002 WL 321797, *7 (E.D.Pa. Feb. 27, 2002). Nevertheless, this Court need not resolve the issue here because even under the more lenient standards of Rule 8(a), Plaintiff's negligent misrepresentation claim cannot withstand the instant motion to dismiss.¹⁴

Last year, addressing the clarifications as to a litigant's pleading requirement stated by the United States Supreme Court in Twombly, 550 U.S. 544, the Court of Appeals for the Third Circuit provided the district courts with guidance as to what pleadings are sufficient to pass muster under Rule 8. See Phillips v. County of Allegheny, 515 F.3d at 230-34. Specifically, the Third Circuit, quoting Twombly, observed as follows:

“[W]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's [Rule 8] obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” . . . “[T]he threshold requirement of Rule 8(a)(2) [is] that the ‘plain statement’ possess enough heft to ‘sho[w] that the pleader is entitled to relief.’” . . . “Factual allegations must be enough to raise a right to relief above the speculative level.”

Phillips 515 F.3d at 231-32 (quoting Twombly 550 U.S. at 555). As previously noted, this pleading standard was further refined by the United States Supreme Court in Ashcroft v.

¹⁴ The Court cautions that to the extent Plaintiff intends to seek this Court's leave to file a second amended complaint, it must be clearly averred that the claim is premised upon a theory of negligence, and does not sound in fraud, to avoid application of Rule 9(b).

Iqbal, 129 S. Ct. 1949 wherein the Supreme Court held that in all civil actions:

[T]he pleading standard Rule 8 announces . . . demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation. . . . The plausibility standard is not akin to a “probability requirement,” but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are “merely consistent with” a defendant’s liability, it “stops short of the line between possibility and plausibility of ‘entitlement to relief.’”

. . . .

Two working principles underlie [the] decision in Twombly. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. . . . Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not “show[n]” - “that the pleader is entitled to relief.” Fed. Rule Civ. Proc. 8(a)(2).

. . . .

Rule 8 does not empower [a claimant] to plead the bare elements of his cause of action, affix the label “general allegation,” and expect his complaint to survive a motion to dismiss.

Iqbal, 129 S.Ct. at 1949-54 (quoting Twombly 550 U.S. at 555-57). Since Iqbal, the Third Circuit has required the district courts to conduct, with regard to Rule 8 allegations, a two-part analysis when presented with a motion to dismiss:

First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. [See Iqbal, 129 S.Ct. at 1949-50]. Second, a District Court must then determine whether the facts alleged

in the complaint are sufficient to show that the plaintiff has a “plausible claim for relief” [in light of the definition of “plausibility” provided in Iqbal.] In other words, a complaint must do *more than allege the plaintiff's entitlement to relief*. A complaint has to “show” such an entitlement with its facts. See Phillips, 515 F.3d at 234-35. As the Supreme Court instructed in Iqbal, “[w]here the well-pleaded facts do not permit the court to infer more than the *mere possibility of misconduct, the complaint has alleged-but it has not ‘show [n]’-that the pleader is entitled to relief.*” Iqbal, 129 S.Ct. at 1949-50. This “plausibility” determination will be “a context-specific task that *requires the reviewing court to draw on its judicial experience and common sense.*” Id.

Fowler, 578 F.3d at 210-11 (emphasis supplied).

This Court finds that Plaintiff has failed to plead anything other than bald conclusory allegations in support of his negligent misrepresentation claim. As previously noted in connection with this Court’s discussion of Plaintiff’s UTPCPL claim, the only factual allegations in the FAC that provide details with regard to this Plaintiff are those in Paragraph 30, none of which address any of the factual allegations necessary to sustain a negligent misrepresentation claim. Not only has Plaintiff failed to plead the alleged false representations relied upon by his prescribing physician, Plaintiff has not even identified his prescribing physician. It is not enough for Plaintiff to set forth a formulaic recitation of the purported omissions and representations referenced in the FDA correspondences, which directed Defendants to cease distribution of its misleading promotional materials four to six years prior to Plaintiff’s prescription for Plavix. Accordingly, Plaintiff’s negligent misrepresentation claim cannot withstand the instant motion to dismiss.

VI. Conclusion

For the foregoing reasons, Defendants’ motion to dismiss Counts II and III of Plaintiff’s FAC is granted. Plaintiff’s negligent misrepresentation claim (Count II) is dismissed without prejudice. Plaintiff shall have leave to file a motion to amend the complaint if he seeks to

assert the claim, but he must cure the deficiencies as outlined by the Court herein. Plaintiff's UTPCPL claim (Count III) is dismissed with prejudice.

Dated: December 30, 2009

/s/ Freda L. Wolfson
United States District Judge